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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,035	12/11/2000	Jas C. Lang	22727/04078	9153

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,035	LANG, JAS C.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,23-25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 23-25, 27, 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 11/25/05 in response to the Office Action of 8/24/05 are acknowledged and have been entered.

Claims 1-28 were pending.

Claims 2-22 and 26 have been cancelled by Applicant.

Claim 1 has been amended by Applicant.

Claims 1 and 23-25, 27, and 28 are currently under examination.

The text of those sections of Title 35 U.S.C. code not included in this Office Action can be found in a prior Office Action.

The following Office Action contains NEW GROUNDS of rejections.

Response to Arguments

Claims 1, 23-25, 27, and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 23-25, 27, and 28 also remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of squamous cell carcinoma and prostate cancer in a subject comprising providing a tissue sample suspected of having cancer from the subject from the head, neck, or prostate and assaying for the presence of SEQ ID NOs:1 or 3, wherein reduced expression of SEQ ID NOs:1 or 3 in the sample, compared to a normal match sample, is indicative of said cancers, does not reasonably provide enablement for a method of detecting said

cancers with just any DESC1 mRNA for the reasons of record and the reasons set forth below.

The amended claims are drawn to a method of cancer detection comprising detecting a decrease in expression of "at least one" DESC1 mRNA in a sample, as compared to controls.

In response to the Office Action of 8/24/05, claim 1 has been amended to make clear that DESC1 mRNA "can be" "derived from" SEQ ID NOs:1 or 3. Applicants further argue that one of skill in the art could easily and without undue burden determine which nucleic acids are contemplated under the conditions set forth in claim 1. Applicants further argue that it is abundantly clear that the target nucleic acid "is DESC1" and since "the nucleotide sequence of DESC1 is provided", one of ordinary skill in the art would have no difficulty in identifying nucleic acids that specifically hybridize to DESC1 under the conditions set forth in the claim. Applicants further state that "the DESC1 cDNA is clearly described in Figures 1A and 1B".

The amendments to the claims and the arguments found in the Response filed 11/25/05 have been carefully considered but are deemed not to be persuasive. As indicated in the Office Action of 8/24/05, the specification does not provide a written description of the genus of "DESC1 mRNA", which the specification discloses encompasses variants with at least 90% identity to SEQ ID NOs:1 or 3 (see pages 7-8,

in particular). The claims do not require that DESC1 mRNA possesses any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of DESC1 polynucleotides that is defined only by sequence identity. Although the response filed 11/25/05 states "the nucleotide sequence of DESC1 is provided", the specification lacks the nucleotide sequence of DESC1. Rather, the specification provides two species from the genus of variants of DESC1 nucleotide sequences, SEQ ID NOs:1 and 3, which do not provide adequate written description and evidence of possession of the claimed genus of DESC1 mRNA.

Although Applicant appears enabled for detecting some cancers by assaying for the presences of SEQ ID NOs:1 and 3, wherein the reduced expression of SEQ ID NO:1 or 3 is indicative of a cancer, the specification does not enable a method for detecting cancers by assaying for the presences of *variants* of SEQ ID NOs:1 and 3 (i.e. DESC1 mRNA). As acknowledged in the Office Action of 12/20/04, SEQ ID NOs:1 and 3 have lower expression in squamous cell carcinomas (Example 1) and prostate cancers cells (Example 5), as compared to controls. However, the specification does not provide sufficient examples indicating that probes against "DESC1 mRNA", which broadly encompasses variants of SEQ ID NOs:1 and 3 with at least 90% identity, would predictably diagnose these cancers.

In view of the lack of guidance, lack of examples, and lack of predictability in the art, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention. These rejections could be obviated by limiting the claims to the detection of SEQ ID NOs:1 and 3.

Claims 1, 23-25, 27, and 28 remain rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for reciting the term "DESC1" as the sole means of identifying the claimed polynucleotide.

In response to the Office Action of 8/24/05, Applicant argues that he is entitled to act as his own lexicographer (MPEP 2111.01 part III). The response of 11/25/05 further argues that Applicant has clearly defined DESC1 in the specification. In an effort to show that DESC1 is clearly defined in the specification, the response cites the following passage: "The method comprises providing a sample from the subject and assaying for the presence, or absence or reduced level of expression of a novel gene, hereinafter referred to as the "DESC1 gene"" (page 1 of specification). The response also indicates that Figures 1A and 1B clearly define the DESC1 gene. Applicant further argues that the fact that different laboratories may use the same laboratory designations to define completely distinct molecules is of no consequence since "Applicant has provided an explicit definition of the term DESC1".

The amendments to the claims and the arguments found in the Response filed 11/25/05 have been carefully considered but are deemed not to be persuasive. Although Applicant is entitled to act as his own lexicographer, MPEP 2111.01 part III requires that "DESC1 mRNA" must be clearly defined in the specification. However, the term "DESC1 mRNA" is not clearly defined in the specification. The specification does not provide a sequence of "the" DESC1 mRNA. Rather, the specification provides sequences of two variants of DESC1 polynucleotides, SEQ ID NOs:1 and 3 (see pages 7-8, in particular). As indicated in the "Brief Description of the Figures", SEQ ID NO:1 is "a cDNA which encodes a DESC1 protein" and SEQ ID NO:3 is also "a cDNA which encodes a DESC1 protein" (page 2). As discussed above, "DESC1 mRNA" is a genus of which the specification lacks a written description. Amending the claims to specifically and uniquely identify DESC1 mRNA by SEQ ID NOs can obviate this rejection.

The following are NEW GROUNDS for Rejection

Claims 1, 23-25, 27, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, and dependent claims 23-25 and 27-28, are indefinite because claim 1 recites "at least one DESC1 mRNA". Are the claims drawn to detecting at least one mRNA transcript (i.e. a single molecule) or are the claims drawn to detecting at least a

single type of molecule (i.e. mRNA corresponding to SEQ ID NO:1 or mRNA comprising SEQ ID NO:2)? Further, is "at least one DESC1 mRNA" inclusive of only mRNA sequences comprising SEQ ID NO:1 or SEQ ID NO:3? As written, the metes and bounds of the claims cannot be determined.

Amended claim 27 recites "...the expression of the at least one DESC1 in the sample". There is insufficient antecedent basis for this limitation in the claim. Although there is antecedent basis for "DESC1 mRNA", there is insufficient antecedent basis for only "DESC1". Further, it is unclear what is meant by "at least one" of something (DESC1) that is not distinctly described in the claim.

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER